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NAVAEROMEDRSCHLAB INSTRUCTION 5100.6F

From: Commanding Officer, Naval Aerospace Medical Research Laboratory

Subj: SAFETY INSPECTION AND CERTIFICATION OF RESEARCH DEVICES FOR USE WITH HUMAN SUBJECTS

Ref: (a) NAMRLINST 3900.3 Series
(b) NAMRLINST 5100.4 Series
(c) NAMRLINST 5100.10 Series
(d) OPNAVINST 5100.23 Series

Encl: (1) Listing of NAMRL Research Devices Utilizing Human Subjects
(2) Device Safety Certification Format
(3) Protocol for Safety Inspection of Research Devices
(4) Research Device Safety Discrepancy Action Format
(5) Risk Assessment Codes

1. Purpose. To establish the requirements and procedures for the safety inspection and certification of Naval Aerospace Medical Research Laboratory research devices for use with human subjects in accordance with references (a) through (d).

2. Cancellation. NAMRLINST 5100.6E

3. Applicability. This directive applies to all NAMRL human use devices. Enclosure (1) lists the devices that are certified at the promulgation of this instruction.

4. Policy.

a. Prior to use of research devices in a research project, a team appointed by the Chairman, Safety Inspection and Certification Committee will inspect the device(s) to determine its safety. The inspection shall be made to ensure that proper standards of safety are achieved prior to the commitment of the device to the appropriate programs, and that a program has been devised and implemented which will systematically maintain the safety posture of all future operations anticipated at the time of the inspection. Upon approval by the inspection team, a Device Safety Certification, enclosure (2) will be issued. An inspection should again be conducted each time there is a change in the device, management philosophy, or test technique. In addition, annual follow-up inspections are required for all previously certified devices expected to be used in succeeding years. No NAMRL personnel will conduct research on these devices until they have been certified safe.

b. All Department Heads, Division Heads, and principal investigators (PI’s) shall cooperate with the inspection team(s) by providing necessary information requested during the inspections.

5. Responsibility. Inspection teams shall be established and function as follows:

a. Establishment. The inspection teams shall be appointed by the CSICC. He may assign a single team to inspect one or more devices at his discretion. The types of potential hazards that may be encountered and the associated expertise of committee members, should be considered in the selection of team personnel.

b. Membership. Each team shall consist of, at a minimum, two members of the Safety Inspection and Certification Committee, and the NAMRL Safety Officer. The Naval Hospital Safety Officer shall be a member of the team. The inspection team shall be accompanied by the cognizant principal investigator (PI). The CSICC shall designate a recorder and at least one alternate on the team.

c. Functions. Each inspection team shall inspect assigned devices for safety and health hazards employing the detailed protocol of enclosure (2). While the protocol is designed primarily to guide in the inspection of motion devices, it can be tailored by the inspection team, to inspect all devices, facilities, equipment and instruments where human subjects are involved. In general, the inspection team is charged with the following tasks:

(1) Understanding the research requirements related to the device.

(2) Identifying potential safety or health hazards.

(3) Recommending means to eliminate or mitigate the identifiable hazards.

(4) Reporting its findings to the Safety Inspection and Certification Committee as a whole.

6. Actions. Inspections of research devices shall be conducted according to the following procedures:

a. Guidelines for Safety Certification Inspections.

(1) General Procedures. It is the responsibility of the PI to request that all electrical equipment used in the subject area be tested by the NAMRL Electrical Safety Officer in accordance with reference (c). The CSICC shall assemble a team when requested by the PI who intends to use a research device needing certification. The team shall use the following general procedures making minor procedural alterations at the discretion of the CSICC to suit particular circumstances so long as the same objectives are accomplished.

(a) The CSICC shall schedule and coordinate all safety inspections with the principal investigator(s) and cognizant Division Head involved. He shall also inform each inspection team member, in writing, of the location, date, and time of the inspection, as well as supplying the name of the principal investigators involved.

(b) The inspection shall commence with a briefing of the team by the PI. This briefing shall include summary information on all salient features to satisfy the requirements of the inspection.

(c) Following the briefing, the team shall view and study the device. The PI shall be present to answer any questions.

(d) Discrepancies and recommendations shall be noted by the team in writing, in the format shown in enclosure (4), and turned in to the CSICC. All recommendations shall be deliberated and categorized by the Risk Assessment Codes

(RAC) described in reference (c), exerpts included as enclosure (5).

(2) Classification of Inspection Team Recommendations. The Safety Inspection and Certification Committee shall review Discrepancy Action forms and classify each recommendation as “mandatory” or “non-mandatory.” Mandatory recommendations are those involving a credible risk of accident or misuse which might cause personal injury or death. In addition, any recommendation which applies to a high risk of equipment or facility damage shall be classified as mandatory, even if personnel safety is not involved. All others are non-mandatory recommendations, including general safety upgrading, where the significant risk is minor damage to devices or surrounding area, or interruption of operations, and immediate action is not required. A two-thirds vote of the committee is required to place a recommendation in the mandatory category; committee reports shall record the votes of members on all recommendations. The committee shall also establish deadlines for compliance with each recommendation. The CSICC shall review the adopted recommendations with the PI and his supervisor to assure that the recommendations are understood and that the committee has not acted on the basis of inaccurate or incomplete information.

(3) Disposition of Committee Recommendations. Committee recommendations shall be forwarded in writing for implementation to the Head of the NAMRL Division (to the cognizant Department Head if the Division Head is also the PI) having responsibility for the device. All mandatory recommendations shall be implemented within the time or event deadlines established by the committee. Non-mandatory recommendations shall be considered for early implementation with due consideration of program requirements. If the cognizant NAMRL element finds that implementation of a recommendation is not feasible due to funding, regulatory, scheduling or some other factors, the Department Head may protest the recommendation to the CSICC. If, after further discussions, the committee fails to change its recommendation, the department head may request a waiver of the recommendation by memorandum. Waivers of mandatory recommendations involving the safety of human subjects shall be reviewed by the Safety Policy Committee and the Committee for the Protection of Human Subjects and referred to the Commanding Officer for decision.

(4) Follow-up Inspections. When notified by the Department Head that corrective action is complete, the team will re-inspect to determine compliance with recommendations. The process of corrective actions and follow-up inspections will continue until the device is certified unless a command decision is made not to use the device.

(5) Reports. All minutes of the Safety Inspection and Certification Committee meetings, any reports, and all inspection team reports, shall be maintained in a permanent file by the CSICC.

(6) Final Report. Following the final reinspection, the committee shall prepare a report that includes the discrepancies identified, the corrective actions, any waivers or deviations from requirements, and the Device Safety Certification. The committee shall provide a copy of the final report to the Department Head concerned, the Committee for the Protection of Human Subjects, and the Safety Policy Committee.

b. Guidelines for Annual/Follow-up Inspections.

(1) Scope. Follow-up inspections are required at yearly intervals after the initial certification of unmodified devices that are long-term use. Follow-up inspections are not as comprehensive as safety certification inspections, but they

serve as independent checks on the continued safe operation of NAMRL's human use devices.

(2) General Procedures. The CSICC will delegate one SICC member to conduct a particular annual follow-up inspection. Copies of the Research Device Safety Discrepancy Action Chits from the initial certification of the device are given to the designated inspector who then uses the following general procedures to accomplish the inspection.

(a) The inspector schedules and coordinates the inspection with the principal investigator (PI) who is using the device or who plans to use it during the next year.

(b) The inspector views and studies the device while the PI is on hand to answer any questions. Three items are of particular interest in this inspection:

(1) The overall physical condition of the apparatus, especially the safety-related features and features that appear to be more than trivial modifications of the original device.

(2) The degree of compliance with the Research Device Safety SOP that was used for initial inspection and certification.

(3) The PI's knowledge of the device and its operating procedures.

(4) Has additional equipment been added to the test site.

(3) Disposition of Device Problems and/or Discrepancies. Results of the inspection can range from zero defects to major safety-related discrepancies. Any problems and/or discrepancies are noted by the inspector in writing.

(a) When no problems are identified, the inspector simply notifies the CSICC of the time of the inspection and of the results.

(b) When minor discrepancies are noted, the inspector discusses them with the PI who assumes the responsibility for corrective action. When the corrective action is complete, a reinspection is conducted, the results of which are either: (1) no discrepancies, or (2) continuing problems requiring further corrective action and reinspection. This process continues until the inspector can report no problems to the CSICC as in (a) above. If this process breaks down through no fault of the inspector, the inspector may assume that major safety-related problems exist and proceeds per (c) below.

(c) When major safety-related problems are detected, the inspector immediately notifies both the NAMRL Safety Officer and the CSICC and gives them a brief description of discrepancies. Human use of the device will be discontinued. The Safety Officer will take action to prevent any possible personal injury and the CSICC will initiate action to conduct a formal Safety Certification Inspection.

(4) Follow-up Inspection Report. Upon notification by the inspector concerning the inspection results, either no problems or major problems, the CSICC prepares a report of the results and distributes it to the Department Head concerned, the Committee for the Protection of Human Subjects, and the Safety Policy Committee.

/s/ A. J. MATECZUN

A. J. MATECZUN

DISTRIBUTION:
LC

NAMRL RESEARCH DEVICES USING HUMAN SUBJECTS (MAY 1989)

Operational Medicine Division (21)

Building 1953

Cardiovascular Lab
Pulmonary Testing Lab

Acceleration Division (22)

Building 1811

Periodic Angular Rotator
Visual Tracking Test (PET)
Off Vertical Rotator
Coriolis Acceleration Platform (CAP)
Human Disorientation Device
Equilibrium Testor
Rotating Litter (PATE)
Stille-Werner Rotator
Vertifuge (DYNASIM)
SPADII
Low Gz Test Chamber

Mobile Field Laboratory

Head Oscillation Test (VORPET)
Visual Tracking Test PET
Nicolet Evoked Response
Off-Vertical Rotator

Environmental Physiology Division (23)

Building 1953

Aviator Selection Lab

Aviation Performance Division (24)

Building 1953

Laser Exposure Apparatus

Sensory Sciences Division (26)

Building 1953

Automated Vision Test Battery
Dynamic Visual Acuity Lab
Contrast Sensitivity Device
Acoustic Test Chamber
Real-Ear Test Chamber

Mobile Field Laboratories

Automated Vision Test Battery
Dynamic Visual Acuity Lab
Contrast Sensitivity Device

DEVICE SAFETY CERTIFICATION

The device/facility listed below has been inspected by members of the Safety Inspection and Certification Committee and is considered safe for research with human subjects as outlined in the test protocols submitted to and approved by the Protection of Human Subjects Committee for the Work Units denoted below:

DEVICE/FACILITY NAME:_____

_____

DEVICE LOCATION: Building:_____ Room No.:_____

PROJECT TITLE:_____

_____

WORK UNIT NUMBER:_____

PROJECT TITLE:_____

_____

WORK UNIT NUMBER:_____

PROJECT TITLE:_____

_____

WORK UNIT NUMBER:_____

PROJECT TITLE:_____

_____

WORK UNIT NUMBER:_____

Inspection shall again be conducted each time there is a modification in the device, management philosophy, or test technique that involves its safe use with human subjects.

Approved by:

_____

Chairman, Safety Inspection and Certification Committee

Date:_____

COPY TO BE POSTED AT DEVICE LOCATION
PROTOCOL FOR SAFETY INSPECTION OF RESEARCH DEVICES
FOR USE WITH HUMAN SUBJECTS

1. Establishment of Research Requirements. The Safety Inspection Team shall acquire background information on the device so as to develop specific recommendations that integrate safety requirements with the intended research applications of the device. Through oral briefings from those responsible for the operation of the device, the team shall obtain a fundamental understanding of the following:

a. Research function of the device

b. Basic operating characteristics of the device

c. Typical research applications

(1) Stimulus levels
(2) Response measurements
(3) Subject tasks
(4) Operator tasks
(5) Unique experimental requirements

2. Identify potential safety/health hazards and recommend means to eliminate or mitigate them. The safety inspection team shall consider the following factors in this task:

a. Device related factors

(1) Structural/mechanical adequacy
    (a) hydraulic systems; fire resistant fluids and pressure vessels
    (b) moving parts
    (c) protrusions, projections, etc.
    (d) welds, bolts, etc.
    (e) tests under load (non-destructive)
(2) Feedback systems
    (a) television monitoring
    (b) sensors; warning and on-going parameter measurement
(3) Electrical
    (a) control systems
    (b) emergency stop procedures; fail-safe interlock(s), deadman switch(es), and voluntary stop
    (c) cooling/ventilation
    (d) lighting
    (e) shock hazards
    (f) motion limit circuitry
(4) Preventive maintenance plans
(5) Periodic inspection plans
(6) Fire hazards
    (a) device shutdown procedures
    (b) area evacuation procedures
    (c) fire extinguishers
    (d) operator duties in event of fire
(7) Human factors and health risks

b. Operator and associated staff factors

(1) Adequacy of training and need for operators to remain current
(2) Written plans and procedures detailing normal and emergency operations
(3) Overall communications systems
    (a) with subjects

(b) with other staff
(4) Experimental run log
(5) Hazardous duty exposures

c. Subject factors

(1) Ingress
(2) Egress
(a) normal
(b) emergency
(3) Audio communications
(4) Adequacy of instructions
(5) Unique problems during start-up
(6) Unique problems during run/procedure
(7) Unique problems during shut-down how long to stop run/procedure
(8) Physiological Monitoring Methods
(9) Adequacy of subject restraint methods

d. Surrounding environment factors

(1) Electrical
(a) lighting; Normal and Emergency
(b) ventilation
(2) Hazards
(a) fire/explosive
(b) trip
(c) electric shock
(d) chemical
(e) physical; radiation and noise
(f) biological
(3) Emergency provisions
(a) exits
(a) breathing apparatus
(c) availability and adequacy of safety and medical services and facilities

e. Any other factors having a direct or indirect bearing on the safe operation of the device.

RESEARCH DEVICE SAFETY DISCREPANCY ACTION FORMAT

SUBMIT TO: CHAIRMAN, SAFETY INSPECTION AND CERTIFICATION COMMITTEE

TITLE: _____
(Brief description of subject)

DEVICE LOCATION:_____

HARDWARE AFFECTED:_____

DISCREPANCY:_____

_____

RISK ASSESSMENT CODE (RAC):_____

RECOMMENDATIONS:_____

_____

REASON:_____

_____

DATE:_____

- -

DECISION (To be filled out by SAFETY INSPECTION AND CERTIFICATION COMMITTEE) VOTE: For_____ Against_____

DATE:_____

__ MANDATORY. Involving a credible risk of accident or misuse which might cause personnel injury or death; or involving a high risk of test article or facility damage.

__ NON-MANDATORY. All others, including general safety upgrading, where the risk is damage to equipment and immediate action is not required.

__ HELD IN ABEYANCE FOR FURTHER STUDY.

__ REJECTED.

REMARKS:_____

__ Discrepancy corrected_____PI/DIV HEAD

__ Correction inspected_____Safety Officer

__ Correction inspected_____inspection team_____

__ Corrective action complete and discrepancy action chit enclosed

_____CSICC

RISK ASSESSMENT CODES

Hazard Severity:

Category I - Catastrophic: The hazard may cause death, or loss of a facility.

Category II - Critical: May cause severe injury, severe occupational illness, or major property damage.

Category III Marginal: May cause minor injury, minor occupational illness, or minor property damage.

Category IV - Negligible: Probably would not affect personnel safety or health, but is nevertheless in violation of a NAVOSH standard.

Mishap Probability: The mishap probability is the probability that a hazard will

result in a mishap, based on an assessment of such factors as location, exposure in terms of cycles or hours of operation, and affected population. Mishap probability shall be assigned an Arabic letter according to the following criteria:

Subcategory A - Likely to occur immediately or within a short period of time.

Subcategory B - Probably will occur in time

Subcategory C - May occur in time

Subcategory D - Unlikely to occur

Risk Assessment Code (RAC): The RAC is an expression of risk which combines the elements of hazard severity and mishap probability. Using the matrix shown below, the RAC is expressed as a single Arabic number that can be used to help determine hazard abatement priorities.

		Mishap Probability				RAC
		A	B	C	D	1 - Critical
	I	1	1	2	3	2 - Serious
Hazard Severity	II	1	2	3	4	3 - Moderate
	III	2	3	4	5	4 - Minor
	IV	3	4	5	5	5 - Negligible